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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,442	10/24/2003	Albert M. Fleischner	Nutramerica	2002

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EXAMINER	
TATE, CHRISTOPHER ROBIN	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,442	FLEISCHNER, ALBERT M.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,17-26 and 28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *-7,17-26 and 28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0506*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 10 May 2006 is acknowledged and has been entered. Claims 1-7, 17-26, and 28-40 have been examined on the merits. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As stated at the beginning of the previous Office action, the Examiner wishes to point out that the instant Application is stated therein to be a Continuation-In-Part of Application No.10/131,868. However, the instant application and Application No.10/131,868 fail to share a common inventor, which is required for any type of continuation application (i.e., the instant inventor is Albert Fleischner, whereas the inventor for Application No. 10/131,868 is Alexander Szynalski). In addition, the instantly claimed herbal formulation and the instantly claimed methods of using the recited herbal formulations are neither taught nor reasonably suggested by the 10/131,868 disclosure (which is drawn to a weight-loss marketing method involving beauty pageants). Accordingly, the instant application has not been afforded priority to the filing date of 10/183,868. Applicant should clarify the instantly recited continuation data and make appropriate corrections thereto if incorrect.

Claim Rejections - 35 USC § 112

Claims 1-7, 17-26, and 28-40 are still deemed non-enabled without complete evidence either that the claimed biological material (e.g.., the required amount of seeds from the instantly claimed plant *Hoodia gordonii*) is known and readily available to the public or complete evidence of the deposit of the biological material - as set forth in the previous Office action and restated below.

It is apparent that the demonstrated plant is required to practice the elected claimed invention. As a required element **it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification***. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a biological deposit thereof (e.g., the required amount of deposited plant seeds). See 37 C.F.R. § 1.802.

*As evidenced by the Internet articles entitled "*African Hoodia Gordonii Plant May Help Fight Fat*", "*In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin*", and "*Focus on biopiracy in Africa*", the only place in the world where *Hoodia gordonii* grows is in South Africa - e.g., this cactus plant only grows wild in the Kalahari Desert and is part of the indigenous culture of that region's local aboriginal Bushman tribes (see entire articles including, e.g., first page of the first cited internet article). Accordingly without clear and convincing evidence to the contrary, it does not appear that this cactus plant would be readily available to the public with respect to making and utilizing the claimed invention.

The specification does not provide a repeatable process for obtaining the demonstrated plant and it is not apparent if the plant is readily available to the public. The specification must contain the date that the biological deposited was made, the name of the plant and the address of where the biological deposit was made.

If the deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and

registration number, stating that the specific seed strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

Claims 23-26 and 28-34 also stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention - for the reason set forth in the previous Office action which are restated below.

Claims 23-26 and 28-34, as instantly amended, broaden the concept of the originally disclosed/claimed invention - i.e., the original disclosure and claims were limited to disclosed effective amounts (e.g., particular ranges) of one or more of the ingredients recited by these claims. The disclosure also supports the phrase "effective amounts" (based upon such ranges) of one of more of the ingredients recited within these claims (see, e.g., the Abstract), in combination with the composition of matter defined by instant claim 19 (containing functional synergistic amounts of *Hoodia gordonii* and a second compound selected from the group consisting of a stimulant and glucosamine) from which the cited claims directly or indirectly depend. However, the original specification including the original claims do not support the concept of any and all undefined amount(s) of the recited ingredients defined by these claims within the instantly claimed composition of matter.

It is suggested that the phrases --an effective amount of-- or --effective amounts of-- be appropriately inserted (before the recited ingredient(s)) within the cited amended claims to overcome this rejection.

Please also see page 13-14 of this Office action concerning Examiner-suggested amendments to independent claims 1, 19, and 35.

Claim Rejections - 35 USC § 103

Claims 1, 2, 35, and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tulp et al. (FASEB Journal, March 2001 - BIOSIS Meeting Abstract)or over Barnett (The Observer, June 2001 - as provided by the internet article entitled "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin") or over Habeck (Drug Discovery Today article entitled "A succulent cure to end obesity", March 2002) or over Kahn (Business Day - Johannesburg, March 2002 - as provided by the internet article entitled "San reach agreement with CSIR over Hoodia") or over Van Heerden et al. (US 6,376,657), for the reason set forth in the previous Office action which are restated below.

Each of the cited references clearly and beneficially teach that the cactus plant *Hoodia gordonii* (and/or extracts thereof - such as the sap: as disclosed in US '657) is effective as a weight-loss and/or anti-obesity agent for losing weight when orally administered. For example: Tulp et al. beneficially teach that a ground-up slurry of Hoodia gordonii plant effectively decreased the body weight of obese rats and that the results of this study indicate that orally administered *Hoodia gordonii* has strong potential for clinical appetite regulation and weight control (see BIOSIS - Meeting Abstract). Barnett also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 3 page document). Habeck also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 2 page document). Kahn also beneficially teaches that the cactus plant *Hoodia gordonii* (and extracts thereof) is well known to be useful as an anti-obesity agent (see entire 4 page document).

Van Heerden et al. also beneficially teach a weight-loss composition which comprises *Hoodia gordonii* sap extract as an active ingredient therein, as well as a method of reducing weight in a subject in need thereof via administering an effective amount of the *Hoodia gordonii* extract (see entire document including, e.g., Abstract, cols 35-36 and 55-70, Figures, claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made repeatedly administer a weight-reducing amount of *Hoodia gordonii* to an obese and/or overweight subject, based upon the beneficial teachings of each of the cited references with respect to its well recognized activity in promoting weight loss and/or acting as an anti-obesity agent. The adjustment of particular conventional working conditions - e.g.., determining appropriate, suitable time periods and intervals for orally administering such a *Hoodia gordonii* weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject..

Thus, the claimed invention as a whole is clearly *prima facie* obvious over each of the cited references, especially in the absence of evidence to the contrary.

Claims 1, 2, 7-9, 35, and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tulp et al. (FASEB Journal, March 2001 - BIOSIS Meeting Abstract), Barnett (The Observer, June 2001 - as provided by the internet article entitled "In Africa the Hoodia cactus keeps men alive. Now its secret is 'stolen' to make us thin), Habeck (Drug Discovery Today article entitled "A succulent cure to end obesity", March 2002), Kahn (Buiness Day - Johannesburg, March 2002 - as provided by the internet article entitled "San reach agreement with CSIR over Hoodia") , and Van Heerden et al. (US 6,376,657), in view of Fleischner (US 6,420,350) and the admitted state of the art, for the reason set forth in the previous Office action which are restated below.

The primary references are relied upon for the reasons set forth above. None of the primary references expressly teach administering such a *Hoodia gordonii* weight loss/anti-obesity product in combination with the other claimed ingredients.

Fleischner discloses weight-loss compositions comprising conventional art-recognized ingredients commonly employed therein such as glucosamine, caffeine, green tea extract, ma huang (ephedra/ephedrine), chromium, and/or vanadium (see entire document).

In addition, as readily admitted by Applicant, each of the additional recited ingredients is well known and recognized in the prior art to be effective for reducing weight and/or enhancing weight loss (see, e.g., paragraphs [0026] - [0075] of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the prior art for the same purpose - as well as to use the combined prior art ingredients for such purpose (i.e., for promoting weight loss/reducing weight in a subject) and for the

following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose, as well as to use such a combination for that purpose (within a method of reducing weight). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

Accordingly, a method of reducing weight (as instantly claimed) via consuming a composition comprising one, two, and/or several conventional weight loss ingredients would have been obvious to one of ordinary skill in the art at the time the claimed invention was made having the above cited references as well as the admitted state of the art before him/her. The result-effective adjustment of particular conventional working conditions (e.g. determining appropriate dosage intervals and/or durations of treatment, or using a particular portion of the *Hoodia gordonii* plant) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Applicant did not present arguments to any of the above rejections within the response filed 10 May 2006. Applicant's previous arguments insofar as they pertain to the art rejections above over Van Heerden et al. (alone or in combination with the other cited reference teachings) have been carefully considered but are not deemed to be persuasive of error in the rejections - for the reasons set forth in the previous Office action, which are restated below.

Applicant previously argued (within their 30 December 2005 response and Rule 132 Declaration, as well as within the Petition filed 13 July 2005) that the teachings of Van Heerden et al. fail to teach weight loss, but instead only teach appetite suppression and that Van Heerden et al. actually teaches that *Hoodia* extracts cause body mass to increase, not decrease. However, this is simply not considered a valid or correct interpretation of the overall teachings provided by Van Heerden in which Van Heerden clearly disclose that *Hoodia* extract preparations are beneficial useful for treating obesity (i.e., for weight loss). See, e.g., cols 56-64 in which Van Heerden expressly teaches that orally consumed pure sap from the *Hoodia gordonii* plant produced statistically significant reductions in bodyweights when compared to vehicle-treated control group from 48 hours to the end of the study (including, e.g., when given on a daily basis). In fact, Van Heerden literally teaches "that the expression --- 'appetite suppressant' --- is used herein to denote activity which tends to limit appetite and/or increase the sense of satiety, and thus tends to reduce caloric intake; this in turn tends to counteract obesity. Accordingly, this invention extends to a method of treating, preventing, or combating obesity in a human or non human animal" and that a preferred embodiment of this aspect of the invention includes a *Hoodia gordonii* extract (e.g., a sap extract) containing an active anti-obesity compound therein (see, e.g., col 70, lines 14-27). It should also be noted that the teachings of Van Heerden et al.

(assignee CSIR) with respect the use of their *Hoodia gordonii* preparations for weight reduction are well documented by others in the prior art (as evidence - see, e.g., articles by Barnett, 2001, Habeck, 2002, and Kahn, 2002 - to name a few). Accordingly, it would seem that Applicant would have been well aware of that the CSIR patented *Hoodia* product was being used for weight reduction at the time of the instantly claimed invention. Applicant previously further argued that the references do not expressly teach the time periods/intervals instantly claimed and/or administering *Hoodia gordonii* a plurality of times each time occurring before the *Hoodia gordonii* causes an appetite stimulating effect. However, as stated above (and previously), the adjustment of particular conventional working conditions - e.g.., determining appropriate, suitable time periods and intervals for orally administering such a *Hoodia gordonii* weight-loss product - is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the overweight/obese subject.. Obviously, the more overweight/obese a subject is, the longer he/she would need to take such a weight-loss product in order to achieve the desired amount of weight loss/reduction. Accordingly, this type of adjustment would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made. With respect to limitation concerning administering the *Hoodia gordonii* a plurality of times, each time occurring before the *Hoodia gordonii* causes an appetite-stimulating effect, this argument is not convincing since the overall teachings of the cited

references clearly show that *Hoodia gordonii* suppress appetite and, therefore, would not typically be considered to provide an appetite-stimulating effect, especially when routinely consumed for the purpose of reducing weight (regardless, the conventional once or more daily consumption of *Hoodia gordonii* would meet this ambiguous limitation).

Applicants other arguments previously presented concerning unexpected success of the claimed invention and that the claimed invention is being widely copied are not deemed relevant to the above art rejections.

As a separate discussion (as set forth in the previous Office action), the Examiner takes issue with the statement made by Applicant within the 30 December 2005 response (and within the Rule 132 Declaration) concerning the teachings of the instant specification (page 3, line 5-) disclosing the well known fact that *Hoodia gordonii* has been used by the San tribesmen in South Africa to temporarily prevent hunger during extended hunting expeditions during which food might not have been readily available. Applicant indicates in the 30 December 2005 response (pages 15-16 therein) that this specification recitation is incorrect and that the San bushmen only consumed *Hoodia* for its water content, not to stave off hunger. However, it would seem to the Examiner that Applicant would have been well aware that the *Hoodia gordonii* cactus plant has been used for thousands of years by the indigenous bushmen of the Kalahari desert in southern Africa to stave off hunger as well as thirst. As evidence - see, e.g., the cited articles by Barnett, 2001; Tulp et al., 2001; and Kahn, 2002 (to name a few), each of which clearly disclose this well known fact. Accordingly, Applicant's attempt to now say that the above statement within the instant specification is incorrect with respect to this plant's use by the indigenous bushmen to stave off hunger goes against this notoriously well documented fact.

As discussed in the previous Office action, based upon the instantly disclosed synergistic activity provided thereby, the instantly claimed composition of matter for body weight reduction comprising a body weight reducing amount of *Hoodia gordonii* together with (i.e., in combination with) a second compound selected from a stimulant (such as green tea extract) and/or glucosamine, wherein the second compound is in a synergistic functional amount that when administered to a subject in need thereof is sufficient to lessen the amount of *Hoodia gordonii* required for body weight reduction - as claimed in claim 19 (as well as the inclusion of one or more of the other instantly claimed ingredients) is deemed free of the prior art of record (as are the corresponding method of use claims - i.e., claims 3 and 37 and dependent claims therefrom) since such a synergistic combination is neither taught nor reasonably suggested by the prior art of record.

Again, to hasten prosecution, it is strongly suggested that claims 3 and 37 be appropriately incorporated into claims 1 and 35, respectively, and that claims 1, 19, and 35 be amended for better clarity as shown below:

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1. A method of body weight reduction, comprising administering to a subject in need thereof an effective amount of *hoodia gordonii* and a second compound selected from the group consisting of a stimulant and glucosamine at least once every about 48 hours for at least about 45 days, whereby said second compound is administered in an amount sufficient to lessen the amount of *hoodia gordonii* required for body weight reduction.

19. A composition for reducing body weight in a subject in need thereof comprising an effective amount of *hoodia gordonii* and a second compound selected from the group consisting of a stimulant and glucosamine, said second compound being in an amount that when administered to said subject is in an amount sufficient to lessen to amount of *hoodia gordonii* required for body weight reduction.

35. A method of body weight reduction, comprising administering to a subject in need thereof an effective amount of *hoodia gordonii* and a second compound selected from the group consisting of a stimulant and glucosamine, said administration repeated a plurality of times, each of said times occurring before said *hoodia gordonii* causes an appetite stimulating effect in said subject, whereby said second compound is administered in an amount sufficient to lessen the amount of *hoodia gordonii* required for body weight reduction.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655